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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

VIVUS, INC. and MITSUBISHI TANABE PHARMA CORPORATION, **Plaintiffs,** **v.** **HETERO USA, INC., HETERO LABS LIMITED UNIT-III, and HETERO LABS LIMITED,** **Defendants.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiffs VIVUS, Inc. ("VIVUS") and Mitsubishi Tanabe Pharma Corporation (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint against defendants Hetero USA, Inc. ("Hetero USA"), Hetero Labs Limited Unit-III ("Hetero Unit III"), and Hetero Labs Limited ("Hetero Labs") (collectively, "Hetero") allege as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Hetero's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking

approval to commercially market generic versions of VIVUS' STENDRA® drug products prior to the expiration of United States Patent Nos. 6,656,935 ("the '935 patent") and 7,501,409 ("the '409 patent") (collectively, "the patents-in-suit").

The Parties

2. Plaintiff VIVUS is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 351 E. Evelyn Avenue, Mountain View, California 94041.

3. Plaintiff Mitsubishi Tanabe Pharma Corporation is a corporation organized and existing under the laws of Japan, having a principal place of business at 3-2-10, Dosho-machi, Chuo-ku, Osaka 541-8505, Japan.

4. On information and belief, defendant Hetero USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, NJ 08854.

5. On information and belief, defendant Hetero Unit-III is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad – 500 018, Andhra Pradesh, India.

6. On information and belief, defendant Hetero Labs is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad – 500 018, Andhra Pradesh, India.

7. Upon information and belief, Hetero USA is a wholly owned subsidiary of Hetero Labs.

8. On information and belief, Hetero Unit-III is a division of Hetero Labs.

9. On information and belief, defendants Hetero USA, Hetero Unit III, and Hetero Labs manufacture and/or distribute generic drugs for sale and use throughout the United States,

including in this Judicial District. On information and belief, defendants Hetero USA, Hetero Unit III, and Hetero Labs also prepare and/or aid in the preparation and submission of ANDAs to the FDA.

10. On information and belief, the acts of Hetero USA complained of herein were done at the direction of, with the authorization of, or with the cooperation, participation, or assistance of, or at least in part for the benefit of, Hetero Unit III and Hetero Labs.

Jurisdiction and Venue

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

12. This Court has personal jurisdiction over Hetero USA. On information and belief, Hetero USA is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. On information and belief, Hetero USA directly or indirectly, manufactures, imports, markets, and sells generic drugs throughout the United States and in this Judicial District. On information and belief, Hetero USA purposefully has conducted and continues to conduct business, directly and indirectly, in this Judicial District, and this Judicial District is a likely destination of Hetero USA's generic products. On information and belief, Hetero USA, Inc. is registered to do business in New Jersey under Business I.D. No. 0400362826. On information and belief, Hetero USA is registered as a Wholesaler in the State of New Jersey (No. 5004050) under the trade name "Hetero USA, Inc." Hetero USA has been sued for patent infringement in this District and did not contest personal jurisdiction in this District in at least the following cases: *Merck, Sharp & Dohme Corp., et al. v. Hetero USA Inc., et al.*, No. 13-1402; *AstraZeneca AB, et al. v. Hetero USA Inc., et al.*, No. 15-3385; *AstraZeneca AB, et al. v. Hetero USA Inc., et al.*, No. 16-1280; and *AstraZeneca AB, et al. v. Hetero USA Inc., et al.*, No. 16-2442.

13. This Court has personal jurisdiction over Hetero Unit-III. This action arises from actions of Hetero Unit-III directed toward New Jersey and because Hetero Unit-III has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with this Judicial District. On information and belief, Hetero Unit-III regularly and continuously transacts business within this Judicial District, including by selling pharmaceutical products in New Jersey, either on its own or through its agent Hetero USA — which, on information and belief, has its principal place of business in Piscataway, New Jersey. On information and belief, Hetero Unit-III derives substantial revenue from the sale of those products in this Judicial District and has availed itself of the privilege of conducting business within the State of New Jersey. Hetero Unit-III has been sued for patent infringement in this District and did not contest personal jurisdiction in this District in at least the following cases: *Merck, Sharp & Dohme Corp., et al. v. Hetero USA Inc., et al.*, No. 13-1402; *AstraZeneca AB, et al. v. Hetero USA Inc., et al.*, No. 15-3385; *AstraZeneca AB, et al. v. Hetero USA Inc., et al.*, No. 16-1280; and *AstraZeneca AB, et al. v. Hetero USA Inc., et al.*, No. 16-2442.

14. This Court has personal jurisdiction over Hetero Labs. On information and belief, Hetero Labs is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. On information and belief, Hetero Labs, directly or indirectly, manufactures, imports, markets, and sells generic drugs throughout the United States and in this Judicial District. On information and belief, Hetero Labs maintains continuous and systematic contacts with New Jersey through its authorized U.S. agent, PharmaQ, Inc., located at Waterview Plaza, 2001 Route 46, Suite 405, Parsippany, NJ 07054-1315. Hetero Labs Limited has been sued for patent infringement in this District and did not contest personal jurisdiction in this District in at least the following cases: *AstraZeneca AB,*

et al. v. Hetero USA Inc., et al., No. 15-3385; *AstraZeneca AB, et al. v. Hetero USA Inc., et al.*, No. 16-1280; and *AstraZeneca AB, et al. v. Hetero USA Inc., et al.*, No. 16-2442.

15. Alternatively, to the extent the above facts do not establish personal jurisdiction over Hetero Unit-III or Hetero Labs, this Court may exercise jurisdiction over these Defendants pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Hetero Unit-III and Hetero Labs would be foreign defendants not subject to personal jurisdiction in the courts of any state; and (c) Hetero Unit-III and Hetero Labs have sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Hetero Unit-III and Hetero Labs satisfies due process.

16. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patents-In-Suit

17. On Dec. 2, 2003, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '935 patent, entitled "Aromatic Nitrogen-Containing 6-Membered Cyclic Compounds" to Tanabe Seiyaku Co., Ltd. as assignee of the inventors Koichiro Yamada, Kenji Matsuki, Kenji Omori, and Kohei Kikkawa. Tanabe Seiyaku Co., Ltd. subsequently changed its name to Mitsubishi Tanabe Pharma Corporation. VIVUS is the exclusive licensee of the '935 patent. A copy of the '935 patent is attached hereto as Exhibit A.

18. On Mar. 10, 2009, the USPTO duly and lawfully issued the '409 patent, entitled "Preparations for Oral Administration" to Mitsubishi Tanabe Pharma Corporation as assignee of the inventors Hideki Murakami and Shoji Takebe. VIVUS is the exclusive licensee of the '409 patent. A copy of the '409 patent is attached hereto as Exhibit B.

The STENDRA® Drug Products

19. VIVUS holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for avanafil tablets, 50 mg, 100 mg, and 200 mg (NDA No. 202276), which it sells under the trade name STENDRA®. STENDRA® is a phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of erectile dysfunction. The claims of the patents-in-suit cover, *inter alia*, the compound avanafil, its marketed indication, and pharmaceutical formulations containing avanafil. Mitsubishi Tanabe Pharma Corporation owns the patents-in-suit and VIVUS is the exclusive licensee.

20. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to STENDRA®.

Acts Giving Rise to This Suit

21. Pursuant to Section 505 of the FFDCA, Hetero filed ANDA No. 209266 ("Hetero's ANDA") seeking approval to engage in the commercial manufacture, use, sale, offer for sale or importation of 50, 100, and 200 mg tablets containing avanafil as the active pharmaceutical ingredient ("Hetero's Proposed Product"), before the patents-in-suit expire.

22. On information and belief, in connection with the filing of its ANDA as described in the preceding paragraph, Hetero has provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Hetero's Paragraph IV Certification"), alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Hetero's ANDA.

23. No earlier than June 17, 2016 Hetero sent written notice of its Paragraph IV Certification to Plaintiffs ("Hetero's Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B). Hetero's Notice Letter alleged that the claims of the patents-in-suit are invalid, unenforceable,

and/or will not be infringed by the activities described in Hetero's ANDA. Hetero's Notice Letter also informed Plaintiffs that Hetero seeks approval to market Hetero's Proposed Product before the patents-in-suit expire.

24. Hetero's Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding any non-infringement defenses, does not allege non-infringement of any claims of the '935 patent and only alleges non-infringement of claims 7 and 10 of the '409 patent.

25. On information and belief, ANDA No. 209266 seeks approval of Hetero's Proposed Product that is the same, or substantially the same, as STENDRA®.

Count I: Infringement of the '935 Patent

26. Plaintiffs repeat and reallege the allegations of paragraphs 1-25 as though fully set forth herein.

27. Hetero's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of avanafil tablets, prior to the expiration of the '935 patent, constitutes infringement of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

28. There is a justiciable controversy between the parties hereto as to the infringement of the '935 patent.

29. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe the claims of the '935 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States.

30. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of the claims of the '935 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States.

On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '935 patent and knowledge that its acts are encouraging infringement.

31. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe the claims of the '935 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, Hetero has had and continues to have knowledge that Hetero's Proposed Product is especially adapted for a use that infringes the '935 patent and that there is no substantial non-infringing use for Hetero's Proposed Product.

32. Plaintiffs will be substantially and irreparably damaged and harmed if Hetero's infringement of the '935 patent is not enjoined.

33. Plaintiffs do not have an adequate remedy at law.

34. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count II: Infringement of the '409 Patent

35. Plaintiffs repeat and reallege the allegations of paragraphs 1-34 as though fully set forth herein.

36. Hetero's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of avanafil tablets, prior to the expiration of the '409 patent, constitutes infringement of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

37. There is a justiciable controversy between the parties hereto as to the infringement of the '409 patent.

38. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe the claims of the '409 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States.

39. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of the claims of the '409 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '409 patent and knowledge that its acts are encouraging infringement.

40. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe the claims of the '409 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, Hetero has had and continues to have knowledge that Hetero's Proposed Product is especially adapted for a use that infringes the '409 patent and that there is no substantial non-infringing use for Hetero's Proposed Product.

41. Plaintiffs will be substantially and irreparably damaged and harmed if Hetero's infringement of the '409 patent is not enjoined.

42. Plaintiffs do not have an adequate remedy at law.

43. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A Judgment that Hetero has infringed the patents-in-suit by submitting ANDA No. 209266;

(B) A Judgment that Hetero has infringed, and that Hetero's making, using, selling, offering to sell, or importing Hetero's Proposed Product will infringe one or more claims of the patents-in-suit;

(C) An Order under 35 U.S.C. § 271(e)(4)(A) that the effective date of FDA approval of ANDA No. 209266 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(D) Preliminary and permanent injunctions enjoining Hetero and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing Hetero's Proposed Product until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Hetero, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any claims of the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(F) A Declaration that the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Product will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

(G) To the extent that Hetero has committed any acts of infringement with respect to the inventions claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), that Plaintiffs be awarded damages for such acts, together with interest;

(H) If Hetero engages in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Product prior to the expiration of the patents-in-suit, a Judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

(I) A Judgment declaring that the patents-in-suit remain valid and enforceable;

(J) Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

(K) Costs and expenses in this action; and

(L) Such further and other relief as this Court may deem just and proper.

Dated: July 27, 2016

By: s/ Charles M. Lizza

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: July 27, 2016

By: s/ Charles M. Lizza

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